

REMARKS

Claims 1-12 are pending. Claims 5 and 6 have been canceled without prejudice or disclaimer. Claims 4, 7, 9, and 10 have been amended. In particular, Applicant has amended claims 4 and 9 to replace the term “pertubant” with “an anti-aggregation agent,” and claim 7 to replace the term “pertubant” with “anti-aggregation agent.” In addition, Applicant has amended claim 10 to delete the term “pertubant.” Applicant has also added claims 13-19.

The amendments to claims 4, 7, 9, and 10 are at least supported by Example 1 of the specification. The addition of claims 13-19 is at least supported by Example 2 of the specification. Accordingly, the amendment does not introduce new matter. Entry of the amendment is therefore respectfully requested.

Rejection Under 35 U.S.C. § 112

In paragraph 4, the Office Action rejects claims 3, 4, and 6-10 as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Applicant respectfully traverses the rejection.

The Office Action rejects claim 3 for reciting the term “gag.” The Office Action contends that it is not readily manifest if the “gag” protein refers to Pr55^{gag} or Pr160^{gag-pol}. Applicant submits that the term “gag,” as used throughout the specification, refers to a HIV precursor protein which can form immature virion and be cleaved into MA, CA, NC, P2, P1, and P6 upon activation of the viral protease. See, for example, page 2, lines 3-20, of the specification. Thus, the term “gag” includes both Pr55^{gag} and Pr160^{gag-pol}.

The Office Action also rejects claims 4, 5, 7, 9, and 10 for reciting the term “pertubant.” Applicant has amended claims 4, 7, 9, and 10 to either delete the term, or replace the term with “anti-aggregation agent.” The phrase “anti-aggregation agent” is at least supported by Example 1 of the specification. Applicant has canceled claim 5, thereby rendering the rejection of claim 5 moot.

In addition, the Office Action rejects claims 6 and 8 for reciting the term “about.” The Office Action argues that the term “about” is “vague and indefinite since the lower and upper limits of the claimed concentration can not be determined.” However, under MPEP 2173.05(b), the definiteness of the term “about” does not depend on whether there are determinable lower and upper limits for the claimed concentration. Instead, it depends on whether infringement could clearly be assessed. See *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540 (Fed. Cir. 1983). Applicant believes that one of ordinary skill

in the art could clearly determine whether a concentration at issue would infringe claim 8 in light of the present specification. Furthermore, the flexibility of the term “about” does not by itself render the term indefinite. See *Ex parte Eastwood*, 163 USPQ 316 (Bd. App. 1968) (held that the term “about” was clear but flexible). Based on the foregoing, Applicant submits that claim 8 satisfies the requirements of 35 U.S.C. § 112. Withdrawal of the rejection of claim 8 is therefore respectfully requested. Applicant has canceled claim 6, thereby rendering the rejection of claim 6 moot.

Rejection Under 35 U.S.C. § 103(a)

In paragraph 5-8, the Office Action rejects claims 1-12 as being obvious over Gross *et al.* (1997) (hereinafter “Gross”) in view of Lingappa *et al.* (2003) (hereinafter “Lingappa”), or over Vlasuk *et al.* (1989) (hereinafter “Vlasuk”) in view of Lingappa. Applicant respectfully traverses the rejection.

The Office Action has failed to establish a *prima facie* case of obviousness. Specifically, the Office Action has not established that Lingappa is prior art for the present application. The present application was filed March 6, 2001, claiming benefit of priority of U.S. Provisional Application Serial No. 60/186,981, filed March 6, 2000. In contrast, Lingappa was filed and published on January 2, 2002 and June 5, 2003, respectively, both of which are after the filing date of the present application. Accordingly, Lingappa cannot be prior art by virtue of its own filing or publication dates.

Lingappa is a continuation-in-part of U.S. Application Serial No. 09/020,144, filed February 6, 1998. However, the Office Action has failed to establish that the content used by the Office Action to reject the present claims is fully supported by U.S. Application Serial No. 09/020,144. See MPEP 2136.03 (mandating that the filing date of a U.S. parent application can only be used as the 35 U.S.C. 102(e) date if it supports the claims of the issued child). Therefore, the Office Action has not satisfied its burden of proof that the relevant Lingappa disclosure cited by the Office Action is prior art for the present application. Accordingly, reconsideration of the rejection is respectfully requested.

Even assuming that Lingappa is prior art for the present application, the Office Action still has failed to establish a *prima facie* case of obviousness. The Federal Circuit has repeatedly emphasized that evidence of a motivation to combine must accompany a challenge based on multiple references. See *In re Dembiczak*, 175 F.3d 994 (Fed. Cir. 1999) and *ATD Corp. v. Lydall, Inc.*, 159 F.3d 534 (Fed. Cir. 1998). See also MPEP §2143.01 (The prior art

must suggest the desirability of the claimed invention). A statement that combination of the prior art to meet the claimed invention would have been within the ordinary skill in the art is not sufficient to establish a *prima facie* case of obviousness. See MPEP §2143.01. The Office Action has not produced any evidence showing any motivation to combine Gross or Vlasuk with Lingappa.

The Office Action states that “it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to test putative antivirals and regulators of assembly, . . .” Applicant strongly disagrees with this statement. Applicant respectfully requests the Examiner to produce documentary proof for the statement. See MPEP §2144.03 (When relying on common knowledge in the art or “well known” in the art, the examiner should cite a reference in support of his/her position if the applicant traverses such an assertion).

Furthermore, the cited references, individually or in combination, do not render claims 9 and 10 obvious. Gross teaches *in vitro* viral assembly based on overnight dialysis. See the left column on page 594 of Gross. Gross does not teach or suggest triggering viral assembly by rapid removal of an anti-aggregation agent (e.g., by dilution). Vlasuk describes the formation of gag p55 aggregate during the purification process. See the right column on page 12107 of Vlasuk. However, the protein aggregate described by Vlasuk is not a viral assembly, as the term generally understood by one of ordinary skill in the art. Lingappa discloses a cell-free viral assembly system using *in vitro* translation in wheat germ extract. This viral assembly system, however, is not triggered by rapid removal of an anti-aggregation agent (e.g., by dilution). Accordingly, each of the cited references fails to teach all the elements of claims 9 and 10. The combination of the cited references does not remedy this deficiency. Therefore, Gross, Vlasuk, and Lingappa do not render claims 9 and 10 obvious. See MPEP 2143.03 (All claim limitations must be taught or suggested in order to establish *prima facie* obviousness).

Based on all of the above reasons, Applicant respectfully submits that the Office Action has failed to establish a *prima facie* case of obviousness. Withdrawal of the rejection of claims 1-4 and 7-12 is therefore respectfully requested. Applicant has canceled claims 5 and 6, thereby rendering the rejection of these two claims moot.


CONCLUSION

For at least the reasons set forth above, Applicant respectfully submits that this application is in condition for allowance. Favorable consideration and prompt allowance of the claims are earnestly solicited.

Should the Examiner believe that anything further is desired in order to place the application in even better condition for allowance, the Examiner is invited to contact Applicant's undersigned representative at the telephone number listed below.

Respectfully submitted,

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